

ATSDR Guidance for Conducting a Review of Health Outcome Data

Under the Superfund Amendment and Reauthorization Act of 1986, Congress mandated ATSDR to conduct Health Assessments at hazardous waste sites. In conducting these assessments, ATSDR was directed to consider multiple sources of information including, “... the comparison of existing morbidity and mortality data on diseases that may be associated with the observed levels of exposure.”

The following guidance is provided to health assessors who are considering recommending a review of Health Outcome Data (HOD) for use in a Public Health Assessment or Health Consultation.

Before recommending a review of HOD, the health assessor should confer with the site team and review the criteria in the Public Health Assessment Guidance Manual (Section 8.6). In these deliberations, the site team is encouraged to consult with epidemiologists, toxicologists, community involvement specialists, statisticians, health educators, and other health professionals, as needed. The Public Health Assessment Guidance Manual lists the following criteria to be considered in making the determination of whether to conduct a HOD review.

- (1) Are there one or more current (or past) potential or completed exposure pathways at the site?
- (2) Can you determine the time period of exposure?
- (3) Can you quantify the population that was, or is being exposed?
- (4) Are the estimated exposure doses(s) and the duration of exposure sufficient for a plausible, reasonable expectation of health effects?
- (5) Are health outcome data available at a geographic level or with enough specificity (i.e., census tract or census block) to allow it to be correlated to the exposed population?
- (6) Do the validated data sources or databases have information on the specific health outcomes or disease(s) of interest likely to occur from exposure to the site contaminants and are those data accessible?

These criteria provide a scientifically-based and objective way of determining if a HOD review is warranted. After reviewing these criteria, if the site team determines that a HOD review is warranted, the health assessor should complete the attached form to document that each of the criteria has been met.

This response should also describe the HOD review and indicate who has agreed to conduct the review (e.g., internal DHAC staff, state cooperative agreement staff, DHS, etc.)

The justification for conducting a HOD review should then be submitted to DHAC management (through Branch Chief), who must concur with the decision to conduct the HOD review. If another division will be involved in conducting the HOD review, their concurrence is also required.

In some instances, the site team may consider recommending that a HOD review be conducted as a service to the community, even though the above criteria are not satisfied. For example, the team may recommend a HOD review be conducted to respond to a public perception that there is an increased incidence of disease in a community. Conducting a HOD review in such a circumstance can be useful in demonstrating ATSDR's responsiveness to the community and promoting community trust and cooperation. Furthermore, if no increase in disease incidence is detected, it may help to allay community concerns. If an increase in disease incidence is detected, it may prompt appropriate community health education and follow-up studies.

Before deciding to conduct a review in these circumstances, the site team (DHAC, DHS, DRO) should consider alternate approaches to respond to the community's concerns. For example, it may be useful to develop a health education program that explains (1) the limitations of a study and (2) the likelihood that a study would not be able to attribute an increase in an adverse health outcome to contamination at the site. Alternatively, the team should consider referring the community's concerns to state or local public health agencies, which may be better able to respond.

If the site team decides that a review of HOD is needed, even though the above criteria are not met, they should provide a written justification for the review. The justification should include a description of the benefit to the community that would result from conducting the review. DHAC management must concur with this recommendation before proceeding.

ATSDR state partners can conduct HOD reviews under the 1043 Cooperative Agreement program. Before conducting such a review, the state should discuss the proposed review with the ATSDR Technical Project Team and evaluate the proposal using ATSDR guidance. However, for HOD reviews conducted by the state in support of a state-lead health assessment or health consultation, DHAC sign-off is not required.

Checklist for Consideration of a Health Outcome Data Review In Support of a Public Health Assessment or Health Consultation

Before conducting a review of Health Outcome Data (HOD), the health assessor should confer with the site team and review the criteria in the Public Health Assessment Guidance Manual (Section 8.6), which are summarized below.

If all questions below are answered 'yes,' then an HOD analysis may be considered as part of the public health assessment.

Date: _____

Site _____ State: _____

Health Assessor: _____

Members of site team: _____

- ☐ yes ☐ no 1. Are there one or more current or past completed or potential exposure pathways at the site?
Describe _____

- ☐ yes ☐ no 2. Can you determine the duration and extent of exposure?
Note: If length and places of exposure cannot be determined, then a HOD review is not appropriate.
Describe _____

- ☐ yes ☐ no 3. Can you quantify the population that was, or is being exposed?
Note: Is the exposed population of sufficient size to detect a statistically significant increase in the disease outcome? Please consult an epidemiologist or statistician.
Describe _____

- ☐ yes ☐ no 4. Are the estimated exposure doses and the duration of exposure sufficient for a plausible, reasonable expectation of adverse health effects?
Note: Is the adverse health outcome biologically plausible?
Describe _____

- ☐ yes ☐ no 5. Are health outcome data available at a geographic level or with enough specificity (i.e., census tract or census block level) to allow these data to be correlated to the exposed population?

Note: If approximate identification of exposed population within the HOD database is not possible, then an HOD review is not appropriate.

Describe _____

- ☐ yes ☐ no 6. Do the validated data sources or databases have information on the specific health outcomes or disease(s) of interest likely to occur from exposures to the site contaminants and are those data accessible?

Describe _____

If the above criteria are not met, what is the rationale for conducting the HOD review? _____

Describe the HOD Review that will be conducted. _____

Who will conduct the HOD review? _____

Concurrence: (Site team members should initial above their names on page 1.)

_____ DHAC Branch Chief

_____ DHS (if applicable)

_____ DRO (if applicable)

cc: Director, DHAC
ADS, DHAC